

**Introduced by Senators Ortiz and Runner**

February 9, 2006

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An act to add Chapter 2 (commencing with Section 125330) to Part 5.5 of Division 106 of the Health and Safety Code, relating to reproductive health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1260, as introduced, Ortiz. Reproductive health and research.

The California Stem Cell Research and Cures Act, an initiative measure, establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in, the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute.

Existing law requires that a patient provide informed consent prior to the receiving various medical treatments.

This bill, with certain exceptions, would require a physician and surgeon, prior to providing assisted oocyte production, as defined, for purposes of donating eggs for medical research or for developing medical therapies, obtain written consent from his or her patient and provide to his or her patient a standardized written summary of health and consumer issues.

Existing law prohibits a person from knowingly, for valuable consideration, purchasing or selling embryonic or cadaveric fetal tissue for research purposes.

This bill would prohibit human oocytes or embryos from being acquired, sold, received, or otherwise transferred for valuable consideration for medical research or development of medical therapies, and would prohibit payment in excess of the amount of reimbursement of expenses to be made to any research subject to encourage her to produce human oocytes for the purposes of medical research.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. Chapter 2 (commencing with Section 125330)  
2 is added to Part 5.5 of Division 106 of the Health and Safety  
3 Code, to read:

4  
5 CHAPTER 2. ASSISTED REPRODUCTIVE TECHNOLOGY SERVICES  
6

7 125330. The following definitions shall apply to this chapter:

8 (a) “Assisted oocyte production” or “AOP” means  
9 pharmaceutically induced manipulation of oocyte production  
10 through the use of ovarian stimulation.

11 (b) “Oocyte” means a female egg or egg cell.

12 125335. (a) Prior to providing AOP to a patient for the  
13 purpose of donating oocytes for medical research or development  
14 of medical therapies, a physician and surgeon shall provide to his  
15 or her patient a standardized written summary of health and  
16 consumer issues associated with assisted oocyte production. The  
17 failure to provide to a patient this standardized written summary  
18 constitutes unprofessional conduct within the meaning of Chapter  
19 5 (commencing with Section 2000) of Division 2 of the Business  
20 and Professions Code.

21 (b) The summary shall include, but not be limited to,  
22 disclosures concerning the potential risks of AOP and oocyte  
23 donation, including the risks associated with using the drugs,  
24 medications, and hormones prescribed for ovarian stimulation  
25 during the AOP or oocyte donation process.

26 (c) For purposes of this subdivision, a standardized written  
27 summary of health and consumer issues associated with assisted  
28 oocyte production shall mean the patient guide published and

1 updated by the American Society for Reproductive Medicine  
2 entitled, “Assisted Reproductive Technology: A Guide for  
3 Patients.”

4 (d) This section shall not affect the suitability or availability of  
5 oocytes procured for research before January 1, 2007, or  
6 procured for research outside of the State of California, if the  
7 oocytes were donated pursuant to protocols or standards that are  
8 generally recognized and accepted by national or international  
9 scientific bodies.

10 125340. (a) Prior to providing AOP to a patient for the  
11 purposes of medical research or development of medical  
12 therapies, a physician and surgeon shall obtain written consent  
13 from his or her patient. The written consent shall include all of  
14 the following:

15 (1) A statement that the patient has received and reviewed the  
16 summary of health and consumer issues required in Section  
17 125335.

18 (2) A statement informing the patient that oocytes may not be  
19 sold or transferred except under the conditions outlined in  
20 Section 125350.

21 (3) A summary of the arrangements the procuring entity has  
22 made for coverage or payment for medical care related to ovarian  
23 stimulation and oocyte retrieval.

24 (4) Disclosure, if the physician and surgeon is participating in  
25 the medical research for which the oocytes will be used.

26 (b) The failure to obtain written consent from the patient  
27 constitutes unprofessional conduct within the meaning of Chapter  
28 5 (commencing with Section 2000) of Division 2 of the Business  
29 and Professions Code. Nothing in this section shall be construed  
30 to relieve the physician and surgeon from other existing duties  
31 under the law, including, but not limited to, the duty to obtain a  
32 patient’s informed consent after fully explaining the proposed  
33 treatment or procedure. The requirement that a physician and  
34 surgeon provide the standardized written summary pursuant to  
35 Section 125335 is in addition to, and does not supplant, other  
36 existing legal requirements regarding informed consent.

37 (c) This section shall not affect the suitability or availability of  
38 oocytes procured for research before January 1, 2007, or  
39 procured for research outside of the State of California, if the  
40 oocytes were donated pursuant to protocols or standards that are

1 generally recognized and accepted by national or international  
2 scientific bodies.

3 125350. No human oocyte or embryo shall be acquired, sold,  
4 received, or otherwise transferred for valuable consideration for  
5 the purposes of medical research or development of medical  
6 therapies. For purposes of this section, “valuable consideration”  
7 does not include reasonable payment for the removal, processing,  
8 disposal, preservation, quality control, storage, transplantation, or  
9 implantation of oocytes or embryos.

10 125355. No payment in excess of the amount of  
11 reimbursement of expenses shall be made to any research subject  
12 to encourage her to produce human oocytes for the purposes of  
13 medical research.

14 125356. The Independent Citizen’s Oversight Committee  
15 established pursuant to Section 125290.15 is encouraged to  
16 review existing studies concerning the health risks and benefits  
17 of ovarian stimulation drugs used for assisted oocyte production,  
18 identify gaps in existing knowledge concerning health risks and  
19 benefits, and to undertake further research as the ICOC deems  
20 necessary to characterize the risks and benefits of those drugs.